DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2015

MAKO Surgical Corporation
Mr. Jonathan Reeves
Principal Regulatory Affairs Specialist
2555 Davie Road
Fort Lauderdale, Florida 33317

Re: K150410
Trade/Device Name: RESTORIS® Porous Partial Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY, NJD, OIY
Dated: February 16, 2015
Received: February 18, 2015

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150410

Device Name
RESTORIS® Porous Partial Knee System

Indications for Use *(Describe)*
The Restoris® Porous Partial Knee System components are intended for unicompartmental knee arthroplasty to treat one or more of the following conditions:

• Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.

• Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis.

• As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

The Restoris® Porous Femoral Component and PST® Tibial Baseplate are intended for cementless or cemented fixation. The Tibial Baseplate may be used in conjunction with ancillary screw fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application.
The implants are single-use devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Submitter: MAKO Surgical Corp.

Address: 2555 Davie Road, Fort Lauderdale, FL 33317

Phone number/ Fax Number: (Ph) 954-628-0665; (F) 954-927-0446

Contact Person: Jonathan Reeves

Date Prepared: February 13, 2015

Proprietary Name: RESTORIS® Porous Partial Knee System

Common Name: Partial Knee System

Classification: Class II

Product Codes/Classification #:

Code of Federal Regulations	Product code	Description
21 CFR 888.3530	HRY	Knee joint femorotibial metal/polymer semi constrained cemented prosthesis
21 CFR 888.3535	NJD	Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis
21 CFR 888.3560	OIY	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Reason for 510(k) submission: Special 510(k): Device modification with no change to fundamental scientific technology or intended use

Device Modification:

- Addition of Sequentially Cross-linked and Annealed UHMWPE (X3) onlay tibial insert
- Gas Plasma Sterilization
- Packaging

Device Description:

The RESTORIS® Porous Partial Knee System is a knee joint femorotibial (unicompartmental) prosthesis. The RESTORIS® Porous Partial Knee System consists of femoral components and tibial baseplate components that are compatible with and

intended for use with MAKO's predicate RESTORIS MCK Tibial Onlay Insert Components (K090763 or K133039).

The RESTORIS® Porous Femoral Component and PST® Tibial Baseplate are intended for cementless or cemented fixation. The Tibial Baseplate may be used in conjunction with ancillary screw fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application. The implants are single-use devices.

The Porous Femur components: sizes 1 through 8, CoCr with a CoCr porous coating for cementless fixation, asymmetric design (meaning that left medial implants can be used on the right lateral compartment and right medial implants can be used on the left lateral compartment; abbreviated hereafter as LM/RL and RM/LL)

PST® Tibial Baseplate components: sizes 1 through 8, Ti6Al4V alloy with MAKO's predicate porous surface (porous structured technology, referred to as "PST®"), asymmetric (LM/RL-RM/LL).

Intended Use:
The RESTORIS ® Porous Partial Knee System components are intended for unicompartmental knee arthroplasty to treat one or more of the following conditions:

- Moderately disabling joint disease of the knee resulting from painful osteo- or post traumatic arthritis.
- Revision of previous unsuccessful surgical procedures, either involving, or not involving, previous use of a unicompartmental knee prosthesis.
- As an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis.

The RESTORIS ® Porous Femoral Component and PST® Tibial Baseplate are intended for cementless or cemented fixation. The Tibial Baseplate may be used in conjunction with ancillary screw fixation. The porous surfaces of both the femoral and tibial tray components provide biological fixation when used in a cementless application.
The implants are single-use devices.

Substantial Equivalence:
The RESTORIS ® Porous Partial Knee System is substantially equivalent to the following 510(k) cleared devices.

Device Name	Manufacturer	510(k) #
RESTORIS ® Porous Partial Knee System	MAKO	K133811

Technological Characteristics:
The RESTORIS® Porous Partial Knee System is similar to legally marketed devices listed previously in that they share the same indications for use, are manufactured from the same or similar material, have same design/technological characteristics and have performance characteristics adequate to withstand anticipated physiological loading.

Performance Data:
The RESTORIS® Porous Partial Knee System has been evaluated through non-clinical performance testing for:

- Insert Snaplock Strength
- Tibial Insert / Baseplate Micromotion
- Tibio-Femoral Range of Motion
- Tibio-Femoral Instability
- Tibio-Femoral Contact Area and Stress
- Tibial Insert Fatigue
- Tibial Insert Wear

Conclusions of Non-clinical Data:
The results of performance testing indicated the device performed within the intended use and did not raise any new safety and efficacy issues. The device was found to be substantially equivalent to the predicate devices.

Summary of Design Control Activities:
The risk analysis activities for this device modification include a risk management plan, hazard analysis and Failure Modes and Effects Analysis (FMEAs). Based upon the review of this data and information obtained through verification and validation activities, there are no unacceptable levels of risks that have been identified resulting from the device modification.